

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Ex parte Michael R. Hynes

Appeal No. \_\_\_\_\_

Serial No.: 10/811,258  
Filed: March 26, 2004  
Group Art Unit: 3763  
Examiner: Mark K. Han  
Applicant: Michael R. Hynes  
Title: CALIBRATED PUSHROD FOR INJECTION VOLUME  
CONTROL IN PREFILLED SYRINGES

Cincinnati, Ohio 45202

Resubmitted October 3, 2007  
Originally submitted: August 1, 2007  
*Via EFS-WEB*

APPEAL BRIEF

This brief is in furtherance of Applicant's Notice of Appeal filed June 1, 2007, appealing the decision of the Examiner dated March 1, 2007 finally rejecting claims 1-11. A copy of the claims appears in the Appendix to this brief.

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/Thomas W. Humphrey/

October 3, 2007

Thomas W. Humphrey

Date

Reg. No. 34,353

**Real Party In Interest**

The real party in interest in this appeal is Mallinckrodt Inc., a corporation of Delaware having a place of business at 675 McDonnell Boulevard, St. Louis, MO 63134.

### **Related Appeals and Interferences**

There are no such appeals or interferences.

### **Status of Claims**

#### **Total Number of Claims in the Application**

Claims 1-11, stand rejected under 35 U.S.C. 102(b), asserted to be anticipated by U.S. Patent 5,531,708 to Woodruff.

Claims 1-11 were originally filed with the application and never amended.

Claims in the application are: Claims 1-11

#### **Status of all the Claims**

1. Claims cancelled: NONE
2. Claims withdrawn from consideration but not cancelled: NONE
3. Claims objected to: NONE
4. Claims allowed or confirmed: NONE
5. Claims rejected: 1-11

#### **Claims on Appeal**

The claims are appeal are Claims 1-11.

### **Status of Amendments**

There are no amendments pending.

**Summary of Claimed Subject Matter as to Independent Claim 1**

Claim 1 of this application recites a pushrod for use with a prefilled syringe containing a known amount of medicinal fluid, the pushrod having a shaft with a scale corresponding to the volume of the pre-filled syringe and a stop for location along the shaft. The stop is located using the scale in correspondence to a prescribed dosage to be injected from the prefilled syringe.

A syringe 12, pushrod 14 having a stop 30 locatable on a scale 32, are all shown in Figs. 1 and 2 and described in the application at page 5. The use of the scale to select a prescribed dosage is noted at page 6, lines 6-9.

**Summary of Claimed Subject Matter as to Independent Claim 6**

Independent claim 6 recites a hand-held syringe assembly including a prefilled syringe, a pushrod that includes a shaft having a scale, and a stop that is located on the shaft using the scale in correspondence with a prescribed dosage injected from the prefilled syringe.

A syringe 12, pushrod 14 having a stop 30 locatable on a scale 32, are all shown in Figs. 1 and 2 and described in the application at page 5. The use of the scale to select a prescribed dosage is noted at page 6, lines 6-9.

**Summary of Claimed Subject Matter as to Independent Claim 11**

Independent claim 11 of this application recites a method for injecting a medicinal fluid from a prefilled syringe, that includes the steps of coupling a calibrated pushrod to the syringe, setting a stop on the syringe to a prescribed dosage, and administering the dosage.

A syringe 12 coupled with pushrod 14, and a stop 30 locatable on a scale 32, are all shown in Figs. 1 and 2 and described in the application at page 5. The use of the scale to select a prescribed dosage is noted at page 6, lines 6-9.



### **Grounds of Rejection**

Whether the subject matter of any of claims 1-11 is anticipated by the Woodruff '708 patent.

## **Argument**

The present claims are directed to a pushrod for a syringe having a "shaft including a scale corresponding to the volume of the prefilled syringe" and a "stop configured for location along the shaft" (see independent claims 1 and 6), and to a method in which a "calibrated pushrod" is coupled to the syringe for the step of "setting a stop on the pushrod to a prescribed dosage".

The Woodruff patent does not show, as claimed herein, a shaft with a scale and a stop that is located using that scale. In contrast to what is claimed herein, Woodruff has a quite different approach: the scale is attached to the stop, and one sets the stop and scale relative to the plunger to calibrate for an injection. Thus, unlike the invention, in which the stop moves relative to the scale, in Woodruff, the two must always be in the same position because they are attached together.

See, e.g., this text at col. 3 lines 2-15 of Woodruff:

The scale is moveable relative to the plunger by a slide element attached to the scale at its zero indicia designation. The scale is calibrated such that when the slide element is retracted to its most rearward position on the plunger, a fixed reference position proximate to the rear end of the container (e.g. a rear container wall) is aligned with the indicia on the scale designating the quantity of material remaining the container. A preset dosage of material to be administered by the container is set by moving the slide element (and thus the scale) to a position on the plunger such that the indicia on the scale corresponding to the preselected

quantity of contents to be discharged from the syringe is aligned with the fixed reference position on the container.

Woodruff proceeds to explain the purpose of this arrangement:

The automatic zero reset feature of the syringe enables the same syringe to be efficiently used for administering separate, successive multiple doses of material, each of which may be of the same or different quantity than the previously administered dosage. Subsequent dosages may be quickly and precisely set on the scale based only on the specific quantity of material to be administered, thereby eliminating the need to make calculations or adjustments to the scale setting. The elimination of such calculations and adjustments significantly reduces the risk of administering incorrect dosages, a problem which occurs frequently when the same syringe is used to administer a plurality of separate dosages of varying quantities of material, and further reduces the time required to administer multiple doses to enhance the overall efficiency of the administration process.

The Woodruff patent, therefore, clearly fails to teach a plunger having the scale and a stop that moves relative to the scale and plunger, as is claimed herein.

In her Final Rejection, the Examiner has asserted that the above-noted distinction from Woodruff is unavailing to Applicant because “the features upon which Applicant relies (i.e., ‘having

a scale and a stop that moves relative to the scale and plunger’, see Page 2 of remarks) are not recited in the rejected claim(s).”

Applicant respectfully disagrees with the Examiner’s reading of the present claims. Claims 1 and 6 clearly recite a “shaft” including a “scale” and a “stop configured for location along the shaft”. Woodruff lacks a stop that may be located along a shaft that has a scale. Claim 11 recites a “calibrated pushrod” and the step of “setting a stop on the pushrod to a prescribed dosage.” Woodruff does not show a calibrated pushrod and a stop that can be set to a dosage on that calibrated pushrod. Thus, the claim recitations clearly do establish that the stop is locatable along the shaft and the scale that is on the shaft.

In view of the clear distinction of the presently claimed invention from the prior art, Applicant submits that the claims are patentable and requests early transmission of a Notice of Allowability.

Respectfully submitted,  
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## **Claim Appendix**

1. (original) A pushrod for use with a prefilled syringe containing a known amount of a medical fluid and having a cross-sectional area, comprising:

a shaft including a scale corresponding to the volume of the prefilled syringe; and,

a stop configured for location along the shaft;

the stop located using the scale in correspondence with a prescribed dosage injected from the prefilled syringe.

2. (original) The pushrod of claim 1, the shaft and the stop including corresponding threads, the threads used for locating the stop along the shaft.

3. (original) The pushrod of claim 1, the shaft including a thumb rest.

4. (original) The pushrod of claim 1, the shaft made of a molded material.

5. (original) The push rod of claim 1, the prefilled syringe including a barrel with a flange, the stop abutting the flange when the prescribed dosage has been injected.

6. (original) A hand-held syringe assembly comprising:

a prefilled syringe containing a known amount of a medical fluid and having a cross-sectional area; and,

a pushrod configured for use with the prefilled syringe and including:

a shaft having a scale corresponding to the volume of the prefilled syringe;  
and,  
a stop configured for location along the shaft;  
the stop located using the scale in correspondence with a prescribed dosage  
injected from the prefilled syringe.

7. (original) The assembly of claim 6, the shaft and the stop including corresponding threads, the threads used for locating the stop along the shaft.

8. (original) The assembly of claim 6, the shaft including a thumb rest.

9. (original) The assembly of claim 6, the shaft made of a molded material.

10. (original) The assembly of claim 6, the prefilled syringe including a barrel with a flange, the stop abutting the flange when the prescribed dosage has been injected.

11. (original) A method of injecting a medical fluid from a prefilled syringe containing a known amount and having a cross-sectional area, comprising:

coupling a calibrated pushrod to the prefilled syringe;  
setting a stop on the pushrod to a prescribed dosage; and,  
administering the dosage through injection.

## **Evidence Appendix**

None.



## **Related Proceedings Appendix**

None.

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